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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/691,344	10/18/2000	Gregory Donoho	LEX-0071-USA	3961

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EXAMINER

MITRA, RITA

ART UNIT PAPER NUMBER

1653

DATE MAILED: 05/06/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/691,344

Applicant(s)

DONOHO ET AL.

Examiner

Rita Mitra

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,6 and 7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,6 and 7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION***Status of the Claims***

Applicants' amendment and response to office action dated October 01, 2002, filed on January 07, 2003 (paper #13) is acknowledged. Claims 4 and 5 have been cancelled. New claims 6 and 7 have been added. Therefore, claims 1-3, 6 and 7 are currently pending and are under examination.

Response to Remarks and Arguments**Withdrawal of Objection/Rejections**

The objection to the defective oath or declaration is withdrawn in view of the new Declaration submitted by the Applicants.

The objection to the specification for the abstract is withdrawn in view of the new abstract (Exhibit D) submitted by the Applicants.

The objection to the Information Disclosure Statement is withdrawn in view of Applicants' submitting the entire document of Reference BN (Exhibit E) of IDS form 1449. This reference has been considered and listed in PTO form 898.

The rejection of claim 1 under **35 U.S.C. § 112, first paragraph** is withdrawn in view of Applicants' amendment to the claim.

The rejection of claims 1 and 2 under **35 U.S.C. § 112, second paragraph** is withdrawn in view of Applicants' amendment to the claims.

The rejection of claims 1 and 3 under **35 U.S.C. § 102(e)** as being unpatentable over Strachan et al. is withdrawn in view of Applicants' amendment to claim 1.

Rejections under 35 U.S.C. § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim 3 remains/is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 is indefinite because it is not clear how the claim is further limiting. It indicates cDNA. Claim 1 recites a sequence which appears to be a cDNA. Applicants' response and arguments have been considered but not found persuasive. The amended claim 1 still recites "An isolated nucleic acid molecule..." thus it is still interpreted as cDNA since "SEQ ID NO: 3" is recited in the claim.

New ground of rejection

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title"

Claims 1-3, 6 and 7 are rejected under 35 U.S.C. 101 because the specification does not provide either a specific or substantial asserted utility or a well-established utility, and thus, does not support the claimed invention. The claimed nucleic acid molecules are not supported by either a specific asserted utility or a well established utility because the specification fails to assert any utility for the claimed nucleic acids and the proteins encoded by them and neither the specification as filed nor any art of record disclose or suggest any activity for the claimed nucleic acids and proteins encoded by them such that another non-asserted utility would be well established. Note, because the claimed invention is not supported by a specific asserted utility for the reasons set forth above, credibility cannot be assessed.

The specification asserts the novel human proteins (NHPs) and the nucleic acids share structural similarity with animal CUB domain proteins, coagulation factors V and XIII, milk fat globule-EGF factor 8, transcriptional repressor AE-binding protein-1, and neuropilins 1 and 2.

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Based on the presence of CUB and discoidin domains in the amino acid sequence of the NHPs, the structural similarity with the above mentioned proteins the application asserts utility is established. The specification, however, fails to provide any functional activity of the claimed nucleic acids and proteins that can be correlated with the CUB domain proteins or coagulation factors V and XIII, milk fat globule-EGF factor 8, transcriptional repressor AE-binding protein-1, and/or neuropilins 1 and 2.

A sequence identity search for SEQ ID NO: 3 and SEQ ID NO: 4 using GenBank database indicates the alignments and percent similarity to sequence, which are not identified as the protein sequence having CUB domain or so forth. For example:

Mackay et al., (see alignment result, N_Geneseq_032802 database, Accession NO: AAS00660, September 7, 2001) teach a human Tango cDNA, having 95.8% sequence identity to SEQ ID NO: 3. Mackay also teach a Tango polypeptide, having 92.1% sequence identity to SEQ ID NO: 4 (see alignment result, A_Geneseq_032802 database, Accession NO: AAU00670, September 7, 2001).

While, a sequence identity search for SEQ ID NO: 3 and SEQ ID NO: 4 using GenBank database indicates a lower percentage sequence identity with coagulation factor V (see Lander et al., Accession NO: AAZ32182, 13 January 2000). Lander et al. teach a human coagulation factor V nucleotide sequence having 5.4% sequence activity to SEQ ID NO: 3. While Gijutsu et al teach a soluble neuropillin sNP-2 protein sequence which has 11.6% to SEQ ID NO: 4. (see alignment result, A_Geneseq_032802 database, Accession NO: AAB24216, February 6, 2001).

Thus, the foregoing indicates that the sequence of SEQ ID NO: 3 and 4 of the instant application has a lower percentage similarity 5.4% and 11.6% to the sequence of Factor V protein and neuropillin protein respectively while it has a much higher percentage similarity (95.8% and 92.1%) to human Tango protein respectively. Therefore, only on the basis of some similarity to sequences identified as CUB domain proteins, coagulation factors V and XIII, milk fat globule-EGF factor 8, transcriptional repressor AE-binding protein-1, and neuropilins 1 and 2, the protein of SEQ ID NO: 4 can not be identified as a member of either of these families. If the protein has similar activity, it would have indicated close sequence similarity with the members of these families.

Based on the specification (pages 2 and the entire specification), no biological activity has been set forth for the nucleic acid and the proteins encoded by them nor any use for the nucleic acid itself has been provided. Only, speculative biological activities have been provided as hybridization probes (pages 5, 8), as antisense molecule useful for gene regulation (page 6), for screening compounds (page 10), for diagnostics and therapeutics (page 12) in the specification. Specification fails to describe or demonstrate any examples in support of the statements given in the above mentioned pages. For example, the use of the protein for further research is described here (page 5, 6, 8, 10 and 12). Without more these are not a patentable utility because one skilled in the art would not have to discover the use of the claimed proteins and the nucleotides encoding them. This situation requires carrying out additional research to identify or reasonably confirm a "real world" context of use and therefore does not define specific and substantial utility.

The specification does not describe the functional properties of the protein neither the specification enumerates any assays for biological activity, it does not guide the selection of a specific assay that would be used to screen the biological activities of the claimed protein for which no known activity is explicitly disclosed nor demonstrated.

In summary, the nucleic acid molecule and proteins encoded claimed do not have a credible, specific or well-established or even demonstrable utility and therefore lacks utility under 35 U.S.C. 101.

In the instant case, the failure of the specification to specifically identify a real world utility but for speculative uses renders the claimed invention deficient under 35 USC 101. No specific biological activity has been identified for the nucleic acid set forth in SEQ ID NO: 3 encoding the protein or for the protein of SEQ ID NO: 4. The person of skill in the art would not be able to identify any specific activity for the protein comprising or related to SEQ ID NO: 4 based on its structure alone for the reasons set forth above. A protein's amino acid sequence is not sufficient to to determine its biological activity (Y.Bidault, "The next generation of bioinformatics software: Examining proteins on the desktop computer," American Biotechnology Laboratory, January 2002, page 12, col 1, paragraph 2). General statements that a composition has an unspecified biological activity or that do not explain why a composition with

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that activity is believed to be useful fails to set forth a "specific utility." Brenner v. Manson, 383 US 519, 148 USPQ 689 (Sup. Ct.1966) (general assertion of similarities to known compounds known to be useful without sufficient corresponding explanation why claimed compounds are believed to be similarly useful is insufficient under 35 USC 101).

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 6 and 7 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial or well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention so that it would operate as intended without undue experimentation.

As discussed above, based on the specification (page 2) it is unclear what activity the claimed nucleic acids encoding the proteins and proteins itself possess, or how a person having skill in the art would have used the claimed nucleic acids molecules and encoded proteins. It would require undue experimentation for a person having skill in the art to be able to use the claimed invention. It is *a priori* unpredictable based on the instant disclosure what activity the claimed nucleic acid and encoded proteins possess because no correlation has been made between the claimed proteins and a specific activity nor has any activity been demonstrated.

Conclusion

No claim is allowed.

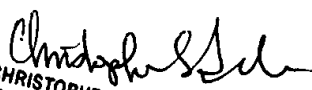
Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rita Mitra whose telephone number is (703) 605-1211. The

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Examiner can normally be reached from 9:30 a.m. to 6:30 p.m. on weekdays. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Christopher Low, can be reached at (703) 308-2923. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center number is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Rita Mitra, Ph.D.
May 3, 2003


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